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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/051,159	01/13/1999	Allan Balmain	CCI-005US	7671

959 7590 09/10/2003

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

29

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/051,159

Applicant(s)

BALMAIN ET AL

Examiner

Richard Schnizer, Ph. D

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-13, 15 and 18-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-13, 15 and 18-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 13 January 1998 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1635

DETAILED ACTION

An amendment was received and entered as Paper No. 28 on 6/16/03.

Claims 16 and 17 were canceled.

Claims 1-13, 15, and 18-25 remain pending and are under consideration in this Office Action.

Oath/Declaration

Applicant's submission of an declaration for patent application listing inventors Balmain and Zhu, and signed by Dr. Zhu, is sufficient to overcome the objection set forth in the previous Office Action.

Rejections Withdrawn

All of the rejections set forth in the previous action are withdrawn in view of Applicant's amendments. New grounds of rejection are set forth below.

Claim Objection

Claim 23 is objected to because it fails to further limit claim 22 from which it depends. Claim 23 requires that "the cell" must be "a tumor cell". Claim 22 has been amended such that the only cell recited is a tumor cell.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 1-13, 15, and 18-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to the genus of promoters that are up-regulated in non-tumor cells relative to tumor cells carrying a mutant p53 or p16 allele. This genus is considered below as two subgenres, i.e. promoters that are up-regulated in non-tumor cells relative to tumor cells carrying a mutant p53 allele as one subgenus, and promoters that are up-regulated in non-tumor cells relative to tumor cells carrying a mutant p16 allele as a second subgenus.

This paragraph focuses primarily on the subgenus of promoters that are up-regulated in non-tumor cells relative to tumor cells carrying a mutant p53 allele. The specification exemplifies promoters carrying a 5' PuPuPuC(A/T)(A/T)GpyPy-Py 3' sequence element that binds p53 and causes up-regulation of linked promoters in non-tumor cells relative to tumor cells carrying an oncogenic p53 allele. No other p53 binding sequence that provides the requisite function of up regulation is disclosed. Instant claim 12, recites that the CMV promoter is a promoter that is up-regulated in non-tumor cells relative to tumor cells carrying either a mutant p53 or p16 allele. The specification does not teach which subgenus (p53 mutant cells, or p16 mutant cells) the CMV promoter falls into. The prior art suggests that it is not a member of the genus of

Art Unit: 1635

promoters that are activated by wild type p53 and down regulated by mutant p53. For example, (Deb et al J. Virol. 66(10): 6164-6170) teach that wild type p53 down regulates the CMV promoter, and a variety of other promoters, whereas oncogenic forms of p53 activate these promoters. See abstract. Thus the art of using wild type p53 to up-regulate promoters that do not contain a 5' PuPuPuC(A/T)(A/T)GpyPyPy 3' sequence element appears to be unpredictable. The specification discloses no example of any promoter that lacks a 5' PuPuPuC(A/T)(A/T)GpyPyPy 3' sequence element and is activated by p53, and provides no description of any other structural element that is required for activation by p53. Furthermore, it should be noted that while the claims recite "tumor cells carrying a mutant p53 or p16 allele", the claims require no relationship between the nature of the p53 or p16 mutation and the tumorigenicity of the cells. That is, the claims embrace promoters that are up-regulated in non-tumor cells relative to tumor cells carrying a mutant p53 or mutant p16 allele wherein the mutant p53 allele or p16 allele is benign and not oncogenic. The specification fails to describe any example of such a promoter, and fails to provide any relevant identifying characteristics of such a promoter. Consequently the specification fails to adequately describe the genus of promoters that are up-regulated in non-tumor cells relative to tumor cells carrying a mutant p53 or p16 allele, and provides an adequate description only of the subgenus of such promoters that comprise a 5' PuPuPuC(A/T)(A/T)GpyPyPy 3' sequence element.

This paragraph focuses primarily on the subgenus of promoters that are up-regulated in non-tumor cells relative to tumor cells carrying a mutant p16 allele. The

Art Unit: 1635

specification discloses no example of any such promoter. A search of the prior art revealed no relationship between p16 and the CMV promoter recited in claim 13. The specification provides no correlation between the function required in the claims (up-regulation in non-tumor cells relative to tumor cells carrying a mutant p16 allele), and any structural characteristic of any promoter. Further, as noted above, the claims require no relationship between the nature of the p16 mutation and the tumorigenicity of the cells, so the claims embrace promoters that are up-regulated in non-tumor cells relative to tumor cells carrying a mutant p16 allele wherein the mutant p16 allele is benign and not oncogenic. The specification fails to describe any example of such a promoter, and fails to provide any relevant identifying characteristics of such a promoter. Because the specification fails to describe any member of the claimed subgenus by reduction to practice or by description of relevant identifying characteristics, one of skill in the art could not conclude that Applicant was in possession of the genus of promoters that are up-regulated in non-tumor cells relative to tumor cells carrying a mutant p16 allele at the time the invention was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 and 19 are indefinite because they depend from a cancelled claim, claim 17.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.



DAVE T. NGUYEN
PRIMARY EXAMINER